IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYOWA HAKKO BIO, CO., LTD., BIOKYOWA, INC., KYOWA HAKKO BIO U.S. HOLDINGS, INC., and KYOWA HAKKO U.S.A., INC., *Plaintiffs*, v. AJINOMOTO CO., INC., AJINOMOTO HEALTH & NUTRITION NORTH AMERICA, INC., and AJINOMOTO FOODS NORTH AMERICA, INC., *Defendants*.	Civil Action No. 17-cv-00313-MSG **Jury Trial Demanded** **PUBLIC VERSION**

AJINOMOTO'S OPENING CLAIM CONSTRUCTION BRIEF

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Ex. 16, Jacob Bear, *Dynamics of Fluids in Porous Media*, 165–67 (1972), AJ109085–90.

Ex. 17. U.S. Patent No. 8,188,308 to Shimose, AJ109008–14.

Ex. 18. crystal size specifications, KHB_0001371.

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[1] The exhibits are attached to the Declaration of Sasha Rao in Support of Ajinomoto's Opening Claim Construction Brief ("Rao Decl.").

Ex. 20. *The New Oxford American Dictionary* (2001), KHB_0001938–40, definition of "add".

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Introduction

The crux of this dispute is the meaning of "average particle size." There are many ways to determine an average particle size, and each results in a different value. Indeed, those differences are so great that, without guidance, one cannot ascertain whether the crystals used in a manufacturing process fall within the claimed range of 7–50 μm. Lamentably, the '723 patent provides no express guidance on how to determine the average particle size, and the claims are thus susceptible to indefiniteness based on Federal Circuit precedent that addresses similar measurements. To the extent that the claims are amenable to construction, the intrinsic record shows that the industry norm favors Ajinomoto's construction: the average particle size is the volume mean diameter. On the other hand, Kyowa's proposal, the number mean diameter, is precluded mathematically by the data in the patent; referred to in the file history as the "the worst choice of the possible options;" and contradicted by stunning pre-litigation admissions of both Kyowa and its technical expert, who concluded that average particle size, in the context of the '723 invention, is a "volume-weighted quantity," consistent with Ajinomoto's construction.

The remaining terms for construction relate to the "adding … before" aspect of the claims. The dispute centers on whether "adding" crystals to the medium refers to crystals that are put into the medium (called "seed crystals") or also encompasses other crystals that spontaneously form within the medium. On this issue, Kyowa's proposed constructions should be dismissed out-of-hand because they contradict every example in the specification, which shows that the added crystals are the seed crystals that are put into the medium, not the other crystals that form in the medium. In fact, Kyowa takes this view in the amended complaint, noting that certain processes are no longer accused of infringement because they "did not use seed crystals." Now, after viewing technical evidence showing that Ajinomoto's seed crystals are much larger than the

claimed range, Kyowa proposes a construction to capture the fine crystals that spontaneously form in the fermentation medium to lower the average particle size.

Factual Background

The '723 Patent

The '723 patent relates to manufacturing an amino acid through a fermentation process in which crystals of the amino acid are added to the fermentation broth as seed crystals to promote growth of larger amino-acid crystals. (Rao Decl., Ex. 1, col. 10:25–38.) In preferred embodiments, reflected in claims 1 and 2, the crystals are not added until after the bacteria in the broth have produced enough of the amino acid to saturate the broth. (Claims 1 and 2, "after the amino acid concentration … reaches the saturation solubility".) Once the seed crystals are added, the amino acid produced by the bacteria in the broth begins to crystallize, and the seed crystals grow into larger crystals that can be easily isolated. (Claims 1 and 2, "allowing the crystals of the amino acid to grow".) The experimental examples reported at columns 9 and 10 and Fig. 1 reflect the effect of seed crystal size on the recovery rate of the crystals. The patent concludes, "by adjusting the average particle size and the amount or the total surface area of the crystals of the amino acid to be added to the medium … crystals of the amino acid which are easily separable from microbial cells can be obtained with a high recovery rate." (Col. 10:33–39; Myerson Decl. ¶ 14–18.)

The '723 patent is a reissue of a patent (Ex. 2) that plaintiff Kyowa Hakko Bio believed was "partly inoperative or invalid by reason of the patentee claiming more than patentee had a right to claim in the patent." (Ex. 3, at KHB_000665.) During the reissue proceedings, Kyowa narrowed the "adding" and "grow" steps of asserted claims 1 and 2, with bracketed and italicized text denoting deletions and additions, respectively, to the original patent claims:

adding crystals of the amino acid having an average particle size of **[**1 to 120**]** *7 to*

> *50* μm to **[**a**]** *the* medium *at some time after the amino acid concentration in the medium reaches the saturation solubility and before crystals of the amino acid deposit in the medium*
> …
> allowing *the* crystals of the amino acid to **[**form**]** *grow to crystals of the amino acid having an average particle size of 30 μm or more ….*
>
> (Ex. 1, claim 1, col. 10:50–56, 59–61; Myerson Decl. ¶ 19–24.)

The parties' competing claim constructions relate to those amendments and are relevant to Kyowa's two theories of infringement, which turn on the following issues:

- whether "average particle size" refers to the number mean or the volume mean or is indefinite, and
- whether "adding crystals … to the medium" refers to adding crystals that are put in the medium as seed crystals or also includes crystals that spontaneously form in the medium.

Overview of Particle-Size Measurements

The purpose of an average-particle-size measurement is to convey information about a sample of particles, such as seed crystals. But, "average particle size" is a term of art that can have different meanings. For example, even in the context of chemical engineering, "[a] powder has many average sizes; hence it is essential that they be well specified." (Ex. 4 at AJ110388, entry for "Average Particle Size".) When measuring an average particle size, it is therefore important to specify how the particles are measured, what type of particle distribution is generated by the measurement, and how the average is calculated from the distribution. (Myerson Decl. ¶ 27–43, 57.) Different measurement techniques measure different properties of a particle, such as volume or surface area. And although it is common to assume that all particles in a sample are spherical, different measured properties of the same particle can still yield different results. (Ex. 5, p. 1.) The Rawle reference in the '723 patent file history illustrates this concept for a single grain of sand. (Ex. 3 at KHB_0001274–75; Ex. 6, p. 1, 2, Fig. 3.)[2]

[2] Ex. 6 and Ex. 7 are color versions of the Rawle and Horiba references in the file history.

Particle-size measurements typically generate a distribution that represents the amount of particles in each size range or channel. When the distribution reflects the *number* of particles in each channel, it is called a number distribution. When the distribution reflects the *volume* of the particles in each channel, it is called a volume distribution. The usefulness of one type of distribution over another, e.g., volume versus number, depends on the application and the measurement technique. For example, laser diffraction, the only measurement technique described in the patent, initially generates a volume distribution based on the pattern and intensity of laser light diffracted by the particle sample. (Ex. 6, p. 3; Myerson Decl. ¶ 34.)

Lastly, there are different mathematical formulas for calculating different types of average particle sizes for different distributions. (Ex. 8, p.101-102.) The number mean (MN) is the mean value of a number distribution, whereas the volume mean (MV or D[4,3]) is the mean value of a volume distribution. (Ex. 3 at KHB_0001246–47, KHB_0001275–76; Ex. 6, p. 2–3; Ex. 7, p. 3–4.) These means have dramatically different values, even when applied to the same sample. (*Id*.; Myerson Decl. ¶ 35–43, 50–52.)

Legal Standard

Claim construction is a matter of law with factual underpinnings. *Markman v. Westview Instruments, Inc*., 517 U.S. 370, 390 (1996); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837–38 (2015). The tenets of claim construction are set forth by the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), and summarized in *Shire ViroPharma Inc. v. CSL Behring LLC*, No. 17-414, 2019 U.S. Dist. LEXIS 9077, at *6–10 (D. Del. Jan. 18, 2019) (Goldberg, J.). The most significant source of authority is the intrinsic evidence of record, i.e., the patent itself, including the claims, the patent specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996);

see also Phillips, 415 F.3d at 1313. The court may rely on extrinsic evidence so long as it is not at odds with the intrinsic record. *Markman*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1317–18.

Level of Ordinary Skill in the Art

The '723 patent relates generally to improvements in amino acid fermentation based on using particular seed crystals and improved crystallization methods. Thus, a person having ordinary skill in the art in this field is a chemical engineer or chemist with a background in applications of crystallization in industry, who may interact closely with a fermentation specialist in the same team if necessary. Such an artisan is trained as a chemist or chemical engineer, or in a related field, having several years of experience in the field of industrial crystallization. Through this training and experience, the artisan has familiarity with standard methods and approaches for crystallizing and purifying amino acid products and with standard techniques for characterizing amino acid crystals. (Myerson Decl. ¶ 25.)

Disputed Terms

The disputed terms appear in both asserted claims (claims 1 and 2) of the '723 patent.

A. "Average particle size" refers to a volume mean diameter determined by the measurement technique described in the '723 patent, or else it is indefinite.

Claim term	Ajinomoto's construction	Kyowa's construction
"average particle size"	volume mean diameter calculated assuming that the particles are spherical, as determined by laser diffraction Alternatively, the term is indefinite.	The sum of particle sizes divided by the number of particles.
"average"	Not necessary to construe separately (volume mean diameter)	The sum of a set of numbers divided by how many there are in the set. Also called a "mean."
"particle size"	Not necessary to construe separately (diameter calculated assuming that the particles are spherical, as determined by laser diffraction)	*Original*: The diameter of a sphere having the same volume as the particle, as determined by sieving, image analysis, or laser diffraction. *New*: The diameter calculated assuming that the particle is spherical.

As an initial matter, the phrase "average particle size" is a term of art that the Court should construe as a single term. (Ex. 4 at AJ110388; Ex. 7, p. 10; Ex. 9, p. 3; Myerson Decl. ¶ 27–28.) Kyowa's proposal improperly severs the term into separate pieces to inflate the relevance of isolated dictionary definitions and then sews those definitions together to define the entire term. That piecemeal approach is routinely criticized and rejected by courts.[3] Here, Kyowa's approach is improper because the specification repeatedly uses the entire term "average particle size," 56 times in all, to describe a physical property of the crystals. In fact, the word "average" *never* appears in isolation and only appears once as part of another term of art, "average specific surface area." Thus, the Court should construe "average particle size" as a single term.

Turning now to the merits, the root of this claim-construction problem is the undisputed fact that there are different techniques for measuring a particle distribution and different equations for calculating the average particle size from the measurement. (Ex. 3 at KHB_0001246–1247; Ex. 7, p. 3–4; Ex. 5, p. 1; Ex. 10, p. 2316-17; Ex. 11 at AJ110510; Myerson Decl. ¶ 29–46, 50–53, 57.) Making matters worse in this case, the ultimate issue—whether Ajinomoto's seed crystals fall within the claimed range—depends on which measurement technique and calculation defines the scope of the claims and is applied to the accused process.

Unfortunately, neither the claims nor the specification of the '723 patent provide express guidance to assist the Court in determining how the average particle size is measured and reported. (*See* Ex. 12, at 141:14–23.) But, the specification does offer enough context for one of

[3] *See Sightsound Techs., LLC v. Apple, Inc.*, No. 11-01292, 2012 U.S. Dist. LEXIS 194661, at *45 (W.D. Pa. Nov. 19, 2012) (noting that separate constructions of "lines" and "telephone lines" could "distort the construction of those terms"); *Biovail Labs. Int'l SRl v. Impax Labs.*, 433 F. Supp. 2d 501, 506 (E.D. Pa. 2006) (declining to separately construe "delayed release" from "delayed release tablet"); *Agere Sys. v. Broadcom Corp.*, No. 03-3138, 2004 U.S. Dist. LEXIS 14187, at *145 n.66 (E.D. Pa. July 20, 2004) ("[T]his does not mean that the phrase as a whole has the aggregate meaning of all its composite parts.").

ordinary skill in the art, who is already familiar with average-particle-size measurements, to conclude that the average particle size is a volume mean diameter determined by laser diffraction. Further, one of ordinary skill in the art would recognize that the information in Fig. 1 eliminates Kyowa's proposed construction from consideration because Kyowa's construction is mathematically precluded by the reported measurements. (Myerson Decl. ¶ 44–53.) Still further, Kyowa and one of its technical experts previously advocated (in a proceeding involving the '723 specification) that the average particle size is volume-weighted, consistent with Ajinomoto's construction and contrary to Kyowa's construction. On the other hand, if the Court finds that one of ordinary skill in the art could not reasonably ascertain the technique and calculation for defining the average particle size, then the claims are invalid for indefiniteness.

1. The intrinsic record suggests to one of ordinary skill in the art that the average particle size is the volume mean diameter calculated assuming that the particles are spherical, as determined by laser diffraction.

The parties disagree on (i) whether the disputed term should be associated with the measured property of the particles (i.e., the diameters of spheres with the same volumes as the particles), (ii) whether the term should be associated with the measuring technique used to obtain the particle size distribution, and (iii) how average particle size is calculated from the distribution.

With respect to the measured property of the particles, the language from Ajinomoto's construction, "assuming the particles are spherical," tracks the language in the specification, "assuming that the crystals are spherical," and is thus truer to the patent's teachings than Kyowa's proposal. (Cols. 8:39–40, 10:6–7.) Ajinomoto's construction also makes clear that the measured particles are treated as volume-equivalent spheres, which is a direct byproduct of laser-diffraction measurements described in the patent and a standard assumption made to avoid the problems that arise when the measured property is left unspecified. (Ex. 7, p. 3–4; Ex. 13, p. 1; Ex. 11 at AJ110510). As demonstrated by the Rawle article in the file history, different measured

properties of particles yield different results, even when particles are assumed to be spherical. (Ex. 3 at KHB_0001275, Fig. 3.) Thus, Kyowa's construction, which does not identify which property of the particle is measured (but only identifies the end-result as the diameter of a sphere), would render the claim indefinite. (Myerson ¶ 29–34, 57.)

With respect to the measurement technique, Ajinomoto proposes that the average particle size is determined from laser diffraction. Kyowa originally agreed that it was determined from laser diffraction but also added the possibility of two other measuring techniques. (D.I. 68-1 at 2095.) Now, Kyowa retracts that position and argues that the term should be untethered from any particular measurement techniques. Kyowa's new construction highlights the problem with average particle size and further subjects the term to indefiniteness: different measurement techniques can yield different mean values for the same sample. The Rawle reference in the file history of the '723 patent acknowledges this problem: "[E]ach technique is liable to generate a different mean diameter as well as measuring different properties of our particle. … There are also an infinite number of 'right' answers." (Ex. 3 at KHB_0001276.) Later, Rawle adds, "[E]ach measurement technique produces a different answer because it is measuring a different dimension of our particle."*(Id.* at KHB_0001278.) Fig. 3 of Rawle shows that this problem exists even when the particles are assumed to be volume-equivalent spheres. (*Id.* at KHB_0001275.) Thus, different measuring techniques could yield different measurements for the same batch of crystals.

The '723 patent addresses this issue, indirectly, by specifying only one measurement technique, laser diffraction. (Cols. 8:33–37, 10:1–4.) As described in the patent, laser diffraction allows for particle distribution analysis and yields the specific-surface-area measurements reported in Fig. 1. (*Id.*) While the patent does not expressly state that the particle distribution

obtained from laser diffraction is also used to calculate the average particle size of the crystals, a person of ordinary skill in the art would make that connection because the '723 patent does not specify any other technique that could generate a particle-size distribution, which is necessary to calculate the average particle size. (Myerson Decl. ¶ 44–46.) Moreover, the patent links the specific surface area, determined by laser diffraction, to the average particle size: "Fig. 1 shows the relationship between average particle size, specific surface area, and total surface area of the crystals the amino acid added …." (Col. 2:62–67.) One of ordinary skill in the art would understand and expect that those properties were calculated from the same particle size distribution output by the same measurement device because the relationship between those properties would be more meaningful than if the measurements were made and compared using different techniques. (Ex. 11 at AJ110510; Myerson Decl. ¶ 47.)

Kyowa's new position, that any technique can be used to measure the particle size distribution of the crystals to be added to the medium, would render the claims of the '723 patent indefinite because different measurement techniques yield different average particle sizes. (Indefiniteness is discussed below in Section A.6.) Kyowa also contradicts its and its expert's arguments to the European Patent Office (EPO) that it is "clear to those skilled in the art" that laser diffraction is used to measure the average particle size. (Ex. 11 at AJ110437, AJ110510.) Thus, the scope of the claim can be altered merely by applying different measurement techniques. If that were not true, i.e., if all measurement techniques produced the same average particle size, then Kyowa could simply stipulate to laser diffraction, because the selected measurement technique would be inconsequential to the scope of the claims. But even the two other measurement techniques in Kyowa's original proposed construction, sieving and image analysis, would not generate the same results as laser diffraction. Sieving has many deficiencies

and "relies on measuring the second smallest dimension of the particle" instead of the diameter of a volume-equivalent sphere. (Ex. 3 at KHB_0001278.) Similarly, image analysis entails measuring one dimension from a two-dimensional image, not a sphere. (*Id*. at KHB_0001280; Myerson Decl. ¶ 43–51.)

Independently of whether one of ordinary skill could discern what is measured or the technique for making the measurements, a separate issue exists with respect to calculating the average from the measurement. While both parties agree that the average particle size is a mean value and should be limited to a particular calculation, they disagree over whether the mean is the *volume* mean diameter (also called MV or D[4,3]) or the *number* mean diameter (sum of diameters divided by the number of particles). The references in the intrinsic record confirm that the industry standard for reporting particle size is to report on a volume basis, and thus, the "average particle size" should be construed as the volume mean diameter. Specifically, the Rawle reference notes that the volume distribution "is the preferred distribution for chemical engineers." (*Id.* at KHB_0001281; Ex. 6, p. 8). Similarly, the Horiba reference points out that "the pharmaceutical industry has concluded that it prefers results be reported on a volume basis for most applications." (Ex. 3 at KHB_0001252; Ex. 7, p. 9.)

Further, the volume mean diameter is the standard way of reporting the mean or average of measurements obtained by laser diffraction, which, again, is the only measurement method specified in the '723 patent. For example, Horiba explains: "As a general rule, specifications should be based in the format of the primary result for a given technique. Laser diffraction generates results based on volume distributions and *any specification should be volume based*." (Ex. 3 at KHB_0001253, emphasis added; *see also* Ex. 7, p. 8–9, providing a primer on number vs. volume distributions.) And, for laser-diffraction measurements, volume mean particle

diameter is the most common way to report the mean: "The most common mean value noted when using laser diffraction is the volume mean, or D4,3," i.e., the volume mean diameter. (Ex. 3 at KHB_0001254.) Similarly, the Rawle reference confirms that laser diffraction results are most often reported on a volume basis: "Laser diffraction initially calculates a distribution based around volume terms and this is why the D[4,3] is reported in a prominent manner." (Ex. 6, p. 3; Myerson Decl. ¶ 34–50).

On the other hand, the literature in the intrinsic record cautions against using the number mean when the underlying measurement technique generates a volume distribution, as with laser diffraction or sieving. For example, the Horiba reference notes that "converting a volume result from laser diffraction to a number basis can lead to undefined errors and is only suggested when comparing to results generated by microscopy." (Ex. 3 at KHB_0001252.) In fact, this reference confirms that, when reporting a single value, "the number mean [is] the worst choice of the possible options" (*Id.* at KHB_0001250). Accordingly, in the absence of any indication to the contrary, one skilled in the art would understand that the '723 patent reports average particle size on a volume basis and *not* a number basis. (Myerson Decl. ¶ 34, 42–57).

The Rawle reference is also critical of the number mean "because the number of particles appears in the equation," which requires that large numbers of particles be counted. (Ex. 3 at KHB_0001275.) Kyowa's definition of "average particle size" requires that every particle in a sample be measured and counted, so that the sum of the diameters can be divided by the number of particles. There is nothing in the '723 patent that suggests particles are counted to calculate the average particle size, and, as a practical matter, counting every particle is virtually impossible on an industrial scale. In contrast, the sole measuring technique disclosed, laser diffraction,

advantageously avoids the need to count particles. (*Id*. at KHB_0001276; Myerson Decl. ¶ 34–52).

Ajinomoto's position also finds support in Kyowa's manual for the LMS-24 particle-distribution analyzer, which is the only measurement device identified in the '723 patent. (Cols. 8:33–40, 10:1–7.) The LMS-24 manual includes images that confirm that the LMS-24 outputs a volume distribution (q3). (Ex. 14 at KHB_0001398, 1404–1405.) And, Dr. Myerson, Ajinomoto's technical expert, confirmed with an employee of the company that makes the LMS-24 that the device only reports information on volume basis and does not report any information on a number basis. (Myerson Decl. ¶ 44–45; *see also* Ex. 12 at 63:9–66:9.) This makes sense because the LMS-24 is a laser-diffraction device that cannot count particles, and as explained above, volume-based calculations are the most common way to report particle-size distributions in industry and also the preferred way to report results obtained from laser diffraction. (Ex. 3 at KHB_0001275–76, 1281; Ex. 6, p. 2–3, 8; *see also*, *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 06-cv-1017, 2008 WL 2410420, at *11 (S.D. Ind. June 11, 2008) (construing "mean particle size" to mean "mean equivalent spherical volume diameter by laser light diffraction scattering."); Myerson Decl. ¶ 37, 42, 50.)

Accordingly, one of ordinary skill in the art would understand from the intrinsic evidence that the "average particle size" discussed and claimed in the '723 patent is a "volume mean diameter calculated assuming that the particles are spherical, as determined by laser diffraction."

2. The measurements reported in the '723 patent mathematically preclude Kyowa's proposed construction.

The measurements reported in the '723 patent demonstrate to one of ordinary skill in the art that Kyowa's proposed construction is erroneous. Specifically, the formulas for calculating average particle sizes share mathematical relationships with each other and with the formula for

specific surface area. The average particle sizes and the specific surface areas of the crystals added in each experiment reported in the '723 patent prove that the average particle size cannot be the number mean, contrary to what Kyowa urges.

Two important mathematical properties of those measurements resolve the underlying claim-construction dispute in favor of Ajinomoto. First, average particle size can be calculated on a surface-area basis (MA) from the specific-surface-area measurements (SSA) reported in Fig. 1 of the '723 patent, using the following formula: **MA = 6/SSA**; and second, the surface-area mean (MA) can be compared against the average particle size reported in Fig. 1. to determine whether the average particle size could possibly be MN, MA, or MV, using the following relationship: **MN < MA < MV**. (Ex. 15, at KHB_0001651–1654; Ex. 16, p. 166–167; Myerson Decl. ¶ 38–41, 53.)

The table below applies these properties to the four experiments reported in Fig. 1 to demonstrate that the average particle sizes of the added crystals are too large to be the number mean (MN), proving that Kyowa's proposed formula—sum of diameters divided by the number of particles—does not work.

Experiment number from the patent	SSA (m^2/cm^3) in the patent	calculated surface-area mean MA = 6/SSA	Average particle size in the patent	MN < MA < MV shows that the average particle size is too large to be MN
①	0.24	25 μm	30 μm	MN < 25 < MV ∴ 30 μm ≠ MN
②	0.16	38 μm	45 μm	MN < 38 < MV ∴ 45 μm ≠ MN
③	0.10	60 μm	70 μm	MN < 60 < MV ∴ 70 μm ≠ MN
④	0.07	86 μm	110 μm	MN < 86 < MV ∴ 110 μm ≠ MN

In each instance above, the reported average particle size is larger than the calculated MA value, and thus, cannot be MN, which is always smaller than MA. Therefore, even though the

'723 patent does not say which average particle size to use, one of ordinary skill would still exclude Kyowa's number mean from consideration on the basis of the measurements in Fig. 1.

3. In proceedings involving a related patent, Kyowa and its original technical expert, Dr. Rousseau, admitted that the average particle size is volume-weighted.

Kyowa's pre-litigation submissions to the European Patent Office (EPO) for its European counterpart patent (which shares the same specification with the '723 patent and contains the same claim term, "average particle size") directly support Ajinomoto's position that the average particle size in the '723 patent is the volume mean diameter. These submissions include admissions from Kyowa's expert, Dr. Ronald Rousseau, as well as Kyowa's arguments that rely on his declaration. Those admissions and arguments are relevant to how one of ordinary skill in the art would interpret the claim term "average particle size" in the same context as the '723 patent because the '723 patent and its European equivalent derive from the same English translation of an international patent application and thus share identical disclosures. *See Glaxo Group Ltd. v. Ranbaxy Pharms., Inc.*, 262 F.3d 1333, 1337 (Fed. Cir. 2001) (noting that a statement to a foreign patent office "bolsters this reading" of the disputed claim limitation in the asserted U.S. patent).

During the opposition of the European patent, Kyowa relied upon a declaration of Dr. Rousseau, who actively assists Kyowa in this litigation. (D.I. 14, Am. Complaint, ¶ 82.) Directly relevant to how one of ordinary skill in the art would understand the disputed terms in this case, Dr. Rousseau prepared a declaration for the European proceedings to interpret the term "average particle size." (Ex. 11 at AJ110468-70.) There, Dr. Rousseau acknowledged that the patent disclosure uses the term "average particle size … without specifically defining how the average was determined." (*Id.* at AJ110469.) But, he concludes that the average is volume-weighted a the measurements were made by laser diffraction: "However, since the particle sizing was done by

laser diffraction and no indication to the contrary is found in the patent, I assume that the average was a *volume-weighted* quantity." (*Id.*, emphasis added; Myerson Decl. ¶ 54.)

Moreover, Kyowa relied on Dr. Rousseau's interpretation of "average particle size" to support its arguments to the EPO that the patent's identification of the LMS-24 analyzer also provides for a volume-weighted average particle size. In Kyowa's own words:

> Consequently, by mentioning the commercial analyzer based on laser diffraction in … the patent[,] not only the method for measuring the particle size is provided but *also the kind of average*, contrary to the opponent's arguments.
>
> In item 3.3 of his declaration (H36) Prof. Rousseau confirms this; his conclusion of *volume-weighted* average is also based on the information about the kind of method used for determining the particle size (here: *laser diffraction* with the assumption of measured volumes of particles being the same as the volumes of spheres – see item 3.2 of his declaration).

(Ex. 11 at AJ110439, emphasis added.) Those admissions are consistent with the industry norm of reporting particle sizes on a volume basis. (Ex. 10, p. 2314, 2317.) Thus, Kyowa's pre-litigation admissions align with Ajinomoto's proposed construction that the average particle size is the volume mean diameter.

In light of those blatant and contradictory admissions, Kyowa is expected to argue that the claim construction positions and testimony before the EPO are irrelevant to its lawsuit in the U.S. But that is only true when the statements in foreign proceedings pertain to issues of law that are unique to the foreign jurisdiction. Here, Kyowa's prior contentions and the testimony of its expert are directly relevant to the issue of how one of ordinary skill in the art would interpret the term "average particle size" in the context of a patent that discloses laser diffraction measurements. The law of the forum is irrelevant.

In fact, in situations like this, the Federal Circuit gives weight to admissions from foreign proceedings. For example, in *Starhome GmbH v. AT&T Mobility LLC*, the Federal Circuit relied in part on the patentee's statements to the EPO to inform the claim construction for the U.S.

counterpart patent. 743 F.3d 849, 858 (Fed. Cir. 2014). Similarly, in *Gillette Co. v. Energizer Holdings, Inc.*, the Federal Circuit found that a "blatant admission" before the EPO supported the court's holding with respect to how one of ordinary skill in the art would construe the claims of a related U.S. patent. 405 F.3d 1367, 1374 (Fed. Cir. 2005). Therefore, Kyowa's and Dr. Rousseau's admissions to the EPO are relevant to the issue of claim construction, constitute extrinsic evidence that is consistent with the patent specification, and raise serious questions about Kyowa's contentions in this litigation.

4. Another of Kyowa's patents, by the same inventor, defines the "average particle diameter" as a volume-weighted quantity.

Kyowa has another patent that explains a similar term to the one in dispute here. U.S. Patent No. 8,188,308 (Ex. 17) issued to the same lead inventor, Tsuyoshi Shimose, as the '723 patent and describes the "average particle diameter" as a volume-weighted measurement made with the LMS-24 particle analyzer: "Average Particle Diameter" is "synonymous with *volume* median diameter" and is "measured using a laser diffraction and scattering particle diameter analyzer, the LMS-24 SK Laser Micron Sizer …." (Ex. 17, col. 8:1–6, emphasis added; Myerson Decl. ¶ 55.) Shimose's '308 patent also describes a process that is similar to the process described in his '723 patent in that both processes add seed crystals to a fermentation broth and recover the crystals from the broth after they have grown. (*Id.* at col. 4:62—5:42.)

Although the '308 patent is based on a Japanese priority patent application filed about 18 months after the priority application that resulted in the '723 patent, the '308 patent still constitutes relevant evidence that those in the field, including the first-named inventor on the '723 patent, understood that an "average" is volume-weighted in the context of measurements obtained from laser diffraction. *See Vitronics*, 90 F.3d at 1581, 1584 (noting that a paper written two years after the patent filing date could be relied upon "to understand the technology and to

construe the claims").

5. [redacted]

6. If one of ordinary skill could not reasonably ascertain the meaning of "average particle size," then the '723 patent is indefinite because the various measures of "average particle size" yield materially different values.

If the Court should find that the intrinsic record of the patent does not provide an objective basis for one skilled in the art to determine what property to measure, how to measure it, or how to calculate the average particle size from the measurement, then the claims are indefinite, and a

report and recommendation of invalidity should be made under 28 U.S.C. § 636(b)(1)(B).

A claim is indefinite as a matter of law under 35 U.S.C. § 112(b) if, when read in light of the specification and the file history, it fails to inform those skilled in the art about the scope of the claims with reasonable certainty. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). This notice requirement is particularly important here because there is a dramatic difference between the volume mean diameter and the number mean diameter. (*See, e.g.,* Ex. 6, p. 3, Ex. 7, p. 8–9.) [redacted] Compounding the problem of which calculation to choose, different measurement techniques also yield different results because they are based on different physical principles. (Ex. 6, p. 3; Ex. 7, p. 8–9; Ex. 5, p. 1; Ex. 11 at AJ110510; Myerson ¶ 57).

Recognizing the unique problems that measurement values can pose in claims, the Federal Circuit has held that a claim is indefinite when different approaches to measurements are involved and the patent specification fails to provide objective boundaries for those of skill in the art. *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 634–635 (Fed. Cir. 2015). For example, in *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, the phrase "molecular weight of about 5 to 9 kilodatons" was indefinite because there were three different measures of molecular weight known in the art and each typically yields a different result. 789 F.3d 1335, 1341 (Fed Cir. 2015). Similarly, in *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, a district court found the term "mean particle size" indefinite because the intrinsic record failed to provide the required guidance as to whether to apply a volume-based mean or a surface-area-based mean. 151 F. Supp. 3d 525, 546–47 (D.N.J. 2015).

This case presents analogous facts to *Teva* and *Otsuka*. Similar to the indefinite term "molecular weight" in *Teva* or "mean particle size" in *Otsuka*, the "average particle size" in the '723 patent is indefinite if one of ordinary skill in the art could not reasonably ascertain whether the average particle size is number-based, volume-based, or based on something else. Although industry favors volume-based measurements and the specification mentions laser-diffraction, the patent fails to provide any explicit, objective guidance on how to calculate the average particle size. [redacted] One of ordinary skill, trying to ascertain the claim scope, would not guess that that was how the seed-crystal sizes were actually obtained. (Myerson Decl. ¶ 49, 57.)

Accordingly, the claims are indefinite, particularly in view of analogous cases involving unspecified measurements. Thus, the claim-construction order should include a report and recommendation under 28 U.S.C. § 636(b)(1)(B) that claims 1 and 2 be found invalid as indefinite.

B. "Adding crystals of the amino acid … to the medium"

Ajinomoto's Proposed Construction	KHB's Proposed Construction
putting crystals of the amino acid … into the medium This term does not encompass crystals that form in the medium.	Introducing crystals to the medium that were not there before

The claims and specification of the '723 patent, consistent with the plain meaning of the word "adding," demonstrate that this disputed term refers to putting crystals in the medium, like any other ingredient. The specification calls those crystals "seed crystals." (Col. 10:33.)

The principle dispute between the parties over the adding step is whether it refers to crystals

that are put into the medium (Ajinomoto's construction) or can also encompass crystals that form from the amino acid that is already present in the medium (the intended practical effect of Kyowa's construction). Kyowa urges the broader construction, contradicting every example of "adding" in the specification, because it encompasses smaller crystals that independently form in the medium, thereby resulting in a smaller average particle size that potentially preserves Kyowa's backup argument for infringement. But, the intrinsic evidence supports Ajinomoto's construction and shows that Kyowa's construction is contrived. In fact, Kyowa espouses a different view in the amended complaint, noting that certain processes are no longer accused of infringement because they "did not use seed crystals." (D.I. 14, ¶ 91–92.)

1. The plain meaning of "adding," when viewed in the context of the rest of the claim language, is that the crystals are put into the medium.

The term "adding" itself has several meanings, but in the context of adding an ingredient, such as "crystals of the amino acid," it is clear that the term "adding" refers to putting crystals from outside the medium into the medium and does not refer to new crystals formed from the medium itself. (Myerson Decl. ¶ 15–18.) Kyowa's dictionary definitions merely bolster this point. For example, the New Oxford Dictionary defines "add" as "put (something) in or on something else so as to improve or alter its quality or nature" and uses the example "chlorine is added to the water to kill bacteria." (Ex. 20, p. 18, definition of "add".) And, none of the more generalized definitions of "add" that Kyowa might rely upon describes the formation of one thing (e.g., crystals) out of another (e.g., ingredients already in the medium).

The rest of the disputed term confirms that the added crystals are an ingredient put into the medium. Specifically, the phrase "to the medium" modifies "adding" and describes where the crystals go. The preposition "to" is defined as "[i]n a direction toward." (Ex. 21 at AJ108952, definition of "to".) Thus, the term "adding" in conjunction with the term "to the medium" must

mean introducing crystals in a direction toward the medium. That is, the crystals must originate *outside* the medium prior to adding.

On the other hand, Kyowa's construction ignores the significance of the phrase "to the medium," as it must, to encompass crystals that form from within the medium. "A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). To construe the adding step to encompass crystals formed *from within* the medium improperly disregards how the inventors chose to describe their invention. *See Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (claim construction begins with and remains focused on the language of the claims because that is what the inventor used to describe his invention). Thus, the claim phrase "to the medium" is further evidence that the term "adding" means that the crystals are an ingredient introduced from outside the medium and not formed from ingredients already in the medium.

Another claim phrase, "before crystals of the amino acid deposit in the medium," also provides instructive context to the construction of "adding." The word "before" places a temporal limitation on the word "adding" by requiring that the adding step occurs before crystals of the amino acid deposit in the medium. It follows then that the added crystals cannot include the crystals that deposit in the medium. But Kyowa's broader construction of the adding step contradicts that logic by encompassing any crystals "that were not there before." This presents a self-contradiction: depositing crystals of the amino acid in the medium cannot occur "before crystals of the amino acid deposit in the medium." Ajinomoto's construction avoids this problem by recognizing that the word "before" excludes from the adding step any crystals that deposit in the medium, such as those forming in the medium.

2. The specification of the '723 patent repeatedly and consistently describes putting pre-made crystals into the medium.

Every embodiment of the adding step in the specification supports Ajinomoto's construction and contradicts Kyowa's construction. This, alone, should be dispositive: "[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582.

In every instance where the '723 patent discusses the origin of the crystals added to the medium, the crystals are prepared to certain size and surface-area specifications and put into the medium. Column 8, lines 11–32, describes how the crystals "to be added" can be purchased commercially or produced. Then the patent describes two examples of how crystals of two different sizes can be prepared by crushing the crystals in a mill. (Col. 8:22–32.) In each of those examples, the crystals are obtained prior to their addition to the medium, consistent with the language "to be added."

This "to be added" language pervades the specification and repeatedly appears in the context of ensuring that the to-be-added crystals fall within a particular average-particle-size or specific-surface-area range. For example, at column 5, line 60, to column 7, line 67, the patent describes various size and concentration ranges of the crystals to be added. [redacted] Not once does the '723 patent suggest that the crystals forming within the fermentation medium should be taken into consideration when calculating the average particle size.

Further, the specification concludes with two examples of producing the amino acid L-glutamine in a 500-liter jar fermenter. In both examples, the "adding" step is performed by putting pre-prepared crystals of a particular average particle size into the medium. (Fig. 1; cols.

9:44–50, 10:8–11.) "Adding" seed crystals in these embodiments did *not* include the formation of new crystals in the medium. To the contrary, all of the added crystals were prepared, and their average particle size known, before they were added to the medium.

This makes sense because the specification repeatedly and consistently stresses the importance of controlling the average particle size and specific surface area of the crystals to be added. In fact, the '723 patent concludes by reemphasizing the importance of controlling the size and surface area of the added crystals, called "seed crystals":

> "The above results have revealed that according to the process of the present invention … the particle size of crystals of an amino acid deposited in the medium during the culturing *can be controlled* by adding crystals of the amino acid to the medium … to allow an appropriate number of crystals of the amino acid to be present in the medium as seed crystals, that is, *by adjusting* the average particle size and the amount or the total surface area of the crystals of the amino acid to be added to the medium, and as a result, crystals of the amino acid which are easily separable from microbial cells can be obtained with a high recovery rate."

(Col. 10:25–38, emphasis added.) Thus, every description of how the added crystals originate supports Ajinomoto's construction that the added crystals are the seed crystals put into the medium and are not formed in the medium.

3. The specification distinguishes crystals that are added from crystals that form within the medium.

One of the experiments reported in the '723 patent—a control experiment in which no crystals were added to the medium—distinguishes added crystals from microcrystals that form in the medium to demonstrate the advantage of adding crystals. Microcrystals are undesirable because, at the end of the culturing process, they result in crystals that are similar in size to the cells of the microorganism, making it difficult to separate and recover the crystals from the cells. (Cols. 1:42–45, 10:12–14.) In describing that experiment, the specification observes that "crystals were not added to the medium," yet there was "still deposition of microcrystals in the

medium." (Col. 10:12–15.) If no crystals were added to the medium, then it necessarily follows that the inventors did not consider the microcrystals that formed and deposited in the medium to be added crystals. (*See* Ex. 22, at KHB_0000282.)

In fact, the specification repeatedly emphasizes that adding crystals to the medium suppresses problematic microcrystals from forming in the medium. (Col. 10:25–38; *see also* Ex. 22 at KHB_0000282–83.) And, to achieve that perceived advantage, the patent limits the average particle size of the crystals in claims 1 and 2—"adding crystals of the amino acid having an average particle size of 7 to 50 μm to the medium"—emphasizing the importance of controlling the size of the crystals to be added. (Cols. 10:50–51, 11:5–6.)

The specification's emphasis on a particular feature of an invention in solving the problems of the prior art is an important factor in construing the claims. *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1354 (Fed. Cir. 2006). Construing "adding" to exclude microcrystals is consistent with the stated goal of the '723 patent to provide an amino acid production process "with a high production efficiency" (i.e., raise the yield of amino acid). (Col. 2:10–12.) As noted in the specification, the presence of microcrystals in the medium frustrates this goal. (Cols. 1:42–45, 10:12–15, "[T]he recovery rate of crystals by centrifugation was lowered due to deposition of microcrystals in the medium.") Indeed, per the specification, the "deposition of a slight amount of amino acid crystal" in the medium before the "adding" step is allowable only "insofar as the effect of the present invention can be achieved in respect of the crystal recovery rate and the like." (Col. 6:46–49.)

Furthermore, to accomplish the goal of improving yield, the '723 patent discloses steps that teach away from forming separate microcrystals. For example, the specification purports that failing to use seed crystals will lower the desired recovery rate "due to deposition of

microcrystals in the medium." (Col. 10:12–15.) Thus, construing "adding" to encompass crystals forming in the medium is contrary to the objectives and instructions in the '723 patent.

4. Kyowa's statements to the Patent Office during prosecution also exclude crystals that form in the medium from the claimed adding step.

Consistent with the specification, Kyowa argued to the Patent Office the importance of avoiding microcrystals that form in the medium during prosecution. This intrinsic evidence is relevant to claim construction because the prosecution history may "demonstrat[e] how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution." *Phillips*, 415 F.3d at 1317. Additionally, examining the prosecution history during claim construction "ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers." *Chimie v. PPG Indus., Inc*., 402 F.3d 1371, 1384 (Fed. Cir. 2005). But this is precisely what Kyowa is attempting to do by creating a claim construction that, when applied to an accused process, encompasses microcrystals that deposit within the medium and thereby lowers the average particle size.

During the reissue proceedings for the '723 patent, Kyowa noted that "[a]ccording to these processes [of claims 1 and 2], L-amino acid crystals can be effectively recovered because the seed crystals grow *with inhibiting codeposition of microcrystals that decrease recovery rate*." (Ex. 3 at KHB_0000416, emphasis added.) In other words, Kyowa advised the examiner during the reissue proceedings that the invention achieves its objective, in part, by using seed crystals of a specific size which have the concurrent effect of suppressing the deposition of microcrystals. The term "adding" cannot therefore encompass both seed crystals of the claimed size and smaller crystals that form in the medium when Kyowa has argued previously that the former is intended to suppress the latter.

In addition, Kyowa cites U.S. Patent No. 7,354,744 to Takahashi as a reference that uses the

"adding" step. (*Id.* at KHB_000416–17; *see also* Ex. 22 at KHB_0000164.) Specifically, Kyowa states that the reference "teaches a method for producing L-Glu in which seed crystals are *added* ….." (Ex. 3 at KHB_0000417, emphasis added.) Kyowa distinguishes this reference by arguing that it "does not teach the size of the seed crystals nor their total surface area," and "[t]herefore, microcrystals are produced" as evidenced by the "precipitation of L-Glu crystals . . . ." (*Id.*) In so doing, Kyowa again distinguishes "adding" seed crystals from crystals forming in the medium itself.

Thus, one of ordinary skill in the art would also understand from the prosecution history leading to the '723 patent that the step of adding crystals of a particular size does not encompass the spontaneous formation of crystals within the medium.

5. Kyowa's statements to foreign patent offices also disparage microcrystal formation.

When commencing the reissue proceeding for the '723 patent, Kyowa advised the Patent Office of a third-party observation filed in its related application in Japan (granted as JP5138368B2) and opposition to its related application in Europe (granted as EP1870476) and requested consideration of those materials by the Patent Office. (Ex. 3 at KHB_0000416-20, 421–24.) Kyowa's '723 patent, the Japanese patent, and the European patent derive from the same priority document and claim adding steps with similar limitations. (*Compare* '723 patent, claim 1, *with* Ex. 23, claim 1, *and* Ex. 24, claim 1.)

In both foreign proceedings, Kyowa stated that seed crystals added to the medium should be restricted to those placed into the medium and exclude crystals formed in the medium itself. In its correspondence with the Japanese Patent Office, Kyowa equated "added crystal" to "seed crystal" and distinguished the seed crystals from the microcrystals that spontaneously form in the medium through secondary nucleation. (Ex. 25, p. 4; Ex. 26, p. 4-5.) Similarly, in the European

opposition, Kyowa again distinguished "added seed crystals" from "nucleation . . . i.e. the formation of new small crystals." (Ex. 11 at AJ110432.) There, Kyowa noted that the claim term "growing" refers to the increase in size of "already formed nuclei or of added seed crystals," and not to microcrystals formed through secondary nucleation. (*Id.*) Thus, Kyowa presented the seed crystals as serving a dual role: the nuclei for crystal growth and a means to suppress microcrystals. If the "adding" step were interpreted to encompass the microcrystals forming in the medium, it would conflict with the patent's stated goal.

Although these statements were made to a foreign patent office, they are relevant to claim construction for the same reasons as Kyowa's admissions concerning the average particle size. *See Starhome*, 743 F.3d at 858 (finding patentee's statements before the EPO supported court's construction). Thus, Ajinomoto's proposed construction—that "adding crystals of the amino acid . . . to the medium" means "putting crystals of the amino acid … into the medium"—should be adopted.

C. "before crystals of the amino acid deposit in the medium" (only necessary to construe if Kyowa's construction of "adding" is adopted)

Ajinomoto's Proposed Construction	Kyowa's Proposed Construction
prior to the presence of more than a slight amount of amino acid crystals in the medium This term is a temporal limitation on the "adding" step.	Prior to the deposit of more than a slight amount of crystals of amino acid produced by the microorganism

Both parties agree that the phrase "before crystals of the amino acid deposit in the medium" places a temporal limitation on the adding step. No further construction of this term is required if the Court adopts Ajinomoto's construction of "adding crystals of the amino acid … to the medium," above in Section C.

On the other hand, if the Court were to adopt Kyowa's broad construction of the adding step to include new crystals that form in the medium, then it is also necessary to construe the phrase

"before crystals of the amino acid deposit in the medium" to establish the point in time at which the adding ends for purposes of determining the "average particle size." Kyowa seeks to delay that point, for infringement purposes, to include more microcrystals in the measurement.

But, stretching the time over which "adding" occurs, as Kyowa urges, creates new problems of how and when to determine the combined average particle size of both the crystals to be put in the medium (the seed crystals) and those that form in the medium. Kyowa's proposed construction of "before crystals of the amino acid deposit in the medium" puts the end of the adding step at the point in time just before there is a deposit of more than a slight amount of crystals of the amino acid *produced by the microorganism*. This determination unfortunately requires some way to discern the crystals of the amino acid produced by the microorganism from the crystals of the amino acid that were put in the medium because only the crystals produced by the microorganism are relevant to the demarcation of when a "deposit of more than a slight amount" has occurred. Yet, Kyowa's construction would have to consider both the crystals put in the medium and those formed in the medium from the amino acid produced by the microorganism when considering the average particle size. Ajinomoto's proposed construction of "before …" establishes the end of the adding step as the point in time just before there is more than a slight amount of amino acid crystals present in the medium. This construction minimizes the problems created by Kyowa's "adding" construction because, for purposes of determining the average particle size, the adding step terminates the instant crystals are put in the medium because there would be more than a slight amount present.

Ajinomoto's construction is also the most consistent with the '723 patent specification because it focuses on the presence of any amino acid crystals that have formed in the medium prior to adding any amino acid crystals to the medium. The specification defines the phrase

"before crystals of the amino acid deposit in the medium" as follows, without distinguishing between the amino acid put in the medium or produced from the microorganism:

> In the above, "before crystals of the amino acid deposit in the medium" refers preferably to the period during which the *presence* of amino acid crystals is not observed at all in the medium; however, *deposition of a slight amount* of amino acid crystals is allowable insofar as the effect of the present invention can be achieved in respect of the crystal recovery rate and the like.

(Col. 6:43–49, emphasis added.) This definition appears in the context of adding amino-acid crystals to a medium that is already saturated or super-saturated with the amino acid. (Col. 6:38–43.) The claims of the '723 patent are drafted in the same context because they require that adding occurs "at some time after the amino acid concentration reaches the saturation solubility." Thus, consistent with Ajinomoto's claim construction, the patent recommends that the adding step occurs before too many microcrystals have deposited in the solution, irrespective of whether they originate from the amino acid produced by the microorganism.

That recommendation addresses the '723 patent's concern that a high level of amino-acid saturation will cause microcrystals to form before the larger crystals can be added. Microcrystals are undesirable because, at the end of the culturing process, they result in crystals that are similar in size to the cells of the microorganism, making separation and recovery of the crystals from the cells difficult. (Cols. 1:42–45, 10:12–14.) The '723 patent purports to avoid that problem and achieve higher yields by adding larger crystals, within a specified average-particle-size range, to the medium before enough microcrystals can form to impact the yield. (Col. 10:32–39.)

Contrary to Kyowa's construction, the '723 patent does not teach that the medium should be monitored during or after the addition of crystals to determine if more than a slight amount of crystals have deposited. Nor does the patent identify any means for doing so. And, even more damaging to Kyowa's proposed construction, the patent does not describe or explain how the crystals formed from the amino acid produced by the microorganism could be distinguished from

the crystals that are being added to the solution so that a person of ordinary skill in the art, or a competitor, could identify the point in time when a more than "a slight amount" of microorganism-produced crystals have deposited.

Thus, Kyowa's construction of term "before crystals of the amino acid deposit in the medium" is both unreasonable and unnecessary since the adding step that it modifies in the claims only pertains to the seed crystals that are put into the medium. To the extent that the Court considers the construction of the "before" term, which is only relevant to this case under Kyowa's construction of the adding step in Section C, Ajinomoto's construction should be adopted because it stays truer to the teaching of the patent to add the crystals to the saturated medium before too many crystals have already deposited in the medium.

Conclusion

Ajinomoto's proposed constructions are rooted in intrinsic evidence and supported by extrinsic evidence. Kyowa's constructions, on the other hand, conflict with the intrinsic evidence, and no amount of extrinsic evidence can overcome their inconsistencies with the '723 patent's specification. Therefore, the Court should adopt Ajinomoto's proposed constructions of the disputed claim terms, or alternatively, with respect to the claim term "average particle size," make a report and recommendation to Judge Goldberg under 28 U.S.C. § 636(b)(1)(B) that the claims be found invalid for indefiniteness.

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